K050201

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Aseptico International

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510(k) Summary

Contact: Grant Ramaley

Date Prepared: December 7, 2004

Trade or Proprietary Name: AEU-14CF Expedition Field Dental System

Classification Name: 872.6640 Unit, Operative Dental

510(k) Number:

Device Description:

The AEU-14CF Expedition is a portable electric dental system intended to provide basic dentistry capabilities in emergency and field situations. The Expedition features an "E" type autoclavable 30,000 RPM brushless micro motor with interchangeable headpieces, a 3-way air/water syringe, a self-contained water system, and an oil-less air compressor. The Expedition is powered by internal 27.6V battery packs, and may be connected to a 120V/230V AC power source or to a 12/24V vehicle battery for extended operation or recharging. A detachable solar panel is also provided for recharging the internal batteries when other sources are not available.

Features of Substantial Equivalence to Aseptico Model AEU-425 [510(k) K022217]

1) Autoclavable low-voltage electric micro motor
2) Forward, reverse, and speed control for handpiece motor
3) Accepts standard "E" Type handpieces
4) Adjustable coolant flow to handpiece for high-speed applications.
5) Operates on either 120/230VAC mains power
6) The 3-way air/water syringe for irrigation, misting, and drying
7) Footswitch for On/Off control of handpiece motor and coolant
8) Self-contained water system and air reserve tank

Other Features:

1) Can operate on internal, rechargeable NiHM batteries. This battery technology is used in the Medtronic Lifepak 20 Defibrillator/Monitor [510(k) K012274]

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Director of Quality and Regulatory Affairs of Aseptico, Incorporated, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Grant Ramaley

(Typed Name)

12-28-2004

(Dated)

(Premarket Notification [510(k)] Number)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Aseptico, Incorporated
C/O Ms. Melissa J. DeGuia
Associate Project Engineer/Reviewer
Underwriters Laboratories, Incorporated
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K050201
Trade/Device Name: EXPEDITION Field Dental System, Model Number AEU-14CF
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: March 11, 2005
Received: March 14, 2005

Dear Ms. DeGuia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

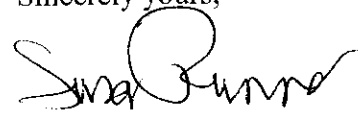
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050201

Device Name: EXPEDITION Field Dental System, Model Number AEU-14CF

Indications for Use:

The EXPEDITION offers the dental professional the capability of carrying a complete dental operative system in one transportable case. The system is suitable for performing general dental procedures anywhere there is a suitable power source. Additionally, the EXPEDITION may be operated on internal batteries, which can be recharged using a detachable solar panel.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Radiology, General Hospital
Infection Control, Dental Devices

510(k) Number K050201